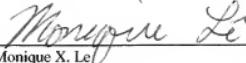


PATENT

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Monique X. Le

Appl No.	:	10/562,368	Confirmation No. 6260
Appellant	:	Maurice Lorette et al.	
Filed	:	June 8, 2006	
Title	:	MULTILAYER FILM	
TC/A.U.	:	1794	
Examiner	:	Ahmed, Sheeba	
Docket No.	:	1135-16-PCT-PA-TD	
Customer No.	:	22145	

**REPLY BRIEF**

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
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43 Corporate Park, Suite 204  
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February 19, 2010

Commissioner:

This is a Reply Brief to the Examiner's Answer dated December 22, 2009 in the above-referenced matter. Appellant maintains the arguments stated in the appeal brief. Appellant hereby clarifies some of the arguments and rebuts the Examiner's reply below. This Brief is filed pursuant to MPEP § 1208.

**STATUS OF CLAIMS**

Claims 1-13 and 17-24 are finally rejected. Claims 1-13 and 17-24 are on appeal. Claims 14-16 were cancelled by the Amendment filed March 16, 2009. A copy of the appealed claims is presented in the Claims Appendix attached hereto.

**GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. The first issue before the Board is whether the subject matter of Claims 1-5, 13, 17, 19, 20, 22 and 23 is anticipated under 35 U.S.C. 102(b) by EP Patent No. 0965443 A1 to Loretta ("Loretta").

2. The second issue before the Board is whether the subject matter of Claims 6, 18 and 21 is unpatentable under 35 U.S.C. 103(a) over Loretta in view of U.S. Patent No. 5,741,566 to Högström et al. ("Högström").

3. The third issue before the Board is whether the subject matter of Claims 7-12 and 24 is unpatentable under 35 U.S.C. 103(a) as being unpatentable over Loretta in view of U.S. Patent No. 5,262,375 to McKedy ("McKedy").

## ARGUMENTS

### I. Rejections of claims 1-5, 13, 17, 19, 20, 22 and 23 under § 102(b) by Loretti (First issue)

The Examiner rejected claims 1-5, 13, 17, 19, 20, 22 and 23 as being anticipated under 35 U.S.C. 102(b) by Loretti. Appellant respectfully submits that Loretti does not anticipate the appealed claims.

Of the appealed claims, claims 1-5, 13, 17 and 19 are argued together as a first group so that dependent claims 2-5, 13, 17, and 19 stand or fall with independent claim 1. Claims 20, 22 and 23 are argued together as a second group so that dependent claims 22 and 23 stand or fall with independent claim 20.

In rejecting claims 1-5, 13, 17, 19, 20, 22 and 23, the Examiner alleges that all the limitations of the rejected claims are either disclosed or inherent in the cited reference (Final Office Action, pages 5-6, Examiner's Answer, pages 3-4).

Preliminarily, for a reference to anticipate a claimed invention under § 102(b), it must adequately meet the terms of the claimed invention interpreted in light of the specification of the application. As set forth in the statute, the single prior art reference must disclose each and every element of the claim under consideration. Moreover, it cannot be rebuilt or reoriented by the utilization of Appellant's teachings in an attempt to create an anticipatory structure. Anticipation is established only when a single prior art reference discloses, expressly or under the principle of inherency, every element of a claimed invention as well as disclosing structure which is capable of performing the recited functional limitations. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984), cert dismissed, 468 U.S. 1228 (1984); *W.L. Gore and Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), cert denied, 469 U.S. 851 (1984).

#### 1. Loretti does not anticipate claims 1-5, 13, 17 and 19

Of the appealed claims, previously presented independent claim 1 recites:

1. (Previously Presented) Sterilizable multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three-layered structure with an inner layer

being in contact with the content of the container, an intermediate layer and an outer layer facing the environment, said layers optionally connected by tie and/or adhesive layers; wherein:

the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7 ml/m<sup>2</sup>d;

said inner layer having a thickness of from 30 to 120 µm;

said intermediate layer having a thickness of from 5 to 35 µm and said outer layer having a thickness of from 20 to 40 µm; and

allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

Thus, claim 1 makes clear that the claimed multilayer film comprises, among other things: (1) an outer layer having a thickness range from 20 to 40 µm; (2) an oxygen transmission rate at 23°C of less than 0.7ml/m<sup>2</sup>d; and (3) wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C. Claim 1 specifies that the outer layer of the multilayer film controls the desorption of water absorbed in the intermediate layer during sterilization at 121°C. Claim 1 further specifies that the intermediate layer determines the oxygen transmission rate through the multilayer film. By allowing the desorption of water absorbed by the intermediate layer during the sterilization process, the outer layer has a direct impact on the oxygen transmission rate through the multilayer film.

#### The '443 Lorette reference

The '443 Lorette patent application discloses a sterilizable polymer composite tubular film having a three-layer structure: (1) a homophase polypropylene inner layer of thickness from 60 to 100 µm, especially from 65 to 85 µm (Col. 3, lines 29-33); (2) an ethylene/vinyl alcohol core layer of thickness from 5 to 35 µm, especially from 10 to 30 µm (Col. 3, lines 9-11); and (3) an outer layer of thickness of 40 to 100 µm, made of polyamide 11, commercially available under the tradename of Rilsan (Col. 2, lines 53-54) and/or polyetherblock amide, commercially available under the trademark of Pebax® (Col. 2, lines 55-56). The '443 Lorette reference also discloses a preferred thickness range "from 45 to 75 µm" for the outer layer (Col. 3, lines 21-23) and in the examples given on page 4, paragraph 0027, Lorette teaches an outer layer of 50µm thickness, made of polyamide 11.

Lorette teaches that the preferred sterilization methods for the referenced multilayer film are "sterilization at temperature of 121°C [ . . . ] in steam-type autoclave or in a water

cascade. . . ." (Col. 4, lines 2-5). Loretti specifically cautions: ". . . Namely, if the ethylene content is chosen too high, the ethylene/vinyl alcohol copolymer layer b) is destroyed in the usual steam sterilization and [loses] its gas barrier properties properties so that the object of the invention cannot be achieved satisfactorily." (Col. 3, lines 2-6).

As described, the '443 Loretti reference does not disclose, among other things, a sterilizable multilayer film having:

- (1) an outer layer having a thickness of from 20 to 40  $\mu\text{m}$ ;
- (2) the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C; and
- (3) an oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer of less than  $0.7\text{ml/m}^2\text{d}$ .

In rejecting claim 1 under § 102(b), the Examiner contends:

(1) Loretti's thickness range of 40 to 100  $\mu\text{m}$  anticipates the claimed thickness range of 20 to 40  $\mu\text{m}$  since the referenced range touches or overlaps the claimed range (Final Office Action, page 8 and Examiner's Answer, page 7); and

(2) the claimed property limitations are inherent in the multilayer structure taught by Loretti given that "the structure of the multilayer film (i. e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film is identical to that of the claimed multilayer film". (Final Office Action, page 6, Examiner's Answer, page 4)

Appellant respectfully submits that Loretti's outer layer does not anticipate the claimed outer layer and the claimed properties are not inherent in Loretti's multilayer film. As further discussed below, properties of a film depend on the chemical makeup of the film. Here, by merely showing similar thicknesses between the Loretti reference and the different layers recited by the claims, the Examiner erroneously concludes that the properties, through inherency, are the same. Clearly, as an analogy, if three different layers of papers are attached with the same thicknesses as recited by the claims, the resultant properties will not be the same as claimed. To prove through inherency, the Examiner must show that the disclosed materials must necessarily yield such claimed properties (i.e., the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C; and an oxygen

transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer of less than 0.7ml/m<sup>2</sup>d) and not simply overlapping thicknesses.

1. Loretti's outer layer does not anticipate the claimed outer layer

With regard to the difference in the thickness range of the claimed outer layer and the outer layer disclosed by Loretti, the Examiner takes the position that:

when the prior art discloses a range which touches or overlaps the claimed range, in order to anticipate the claims; the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute" and a case by case determination is made as to anticipation. Furthermore, what constitutes a "sufficient specificity" is fact dependent. In this case, the overlapping range is taught with "sufficient specificity" given that the reference states that the outer layer should have a thickness of 40 to 100 microns" (final Office Action, pages 8-9 and Examiner's Answer, page 7).

In the Examiner's Answer, the Examiner explained the following regarding her interpretation of "sufficient specificity to constitute an anticipation under the statute":

Appellants . . . state that even though the '443 Loretti reference discloses a broad genus thickness range of 40 to 100 microns, it specifically teaches "especially from 45 to 75 microns" (col. 3, lines 21-23) and in the example given on page 4, paragraph 0027, teaches an outer layer of 50 microns. . . First, it is the Examiner's position that when the prior art discloses a range which touches or overlaps the claimed range, in order to anticipate the claims, the claims subject matter must be disclosed in the reference with sufficient specificity to constitute an anticipation under the statute" and a case by case determination is made as to anticipation. Furthermore, what constitutes a "sufficient specificity" is fact dependent". In this case, the overlapping range is taught with "sufficient specificity" given that the reference states that the outer layer should have a thickness of 40 to 100 microns. Second, under 35 U. S. C. 102, the entire disclosure of a prior art reference and not just the preferred embodiments can be relied upon to reject the claims. (Examiner's Answer, pages 6- 7).

Appellant respectfully submits that the Examiner's interpretation of "sufficient specificity" in the instant case is incompatible with the case law governing "sufficient specificity" in the context of anticipation of ranges, as further discussed below. Appellant respectfully points out that the Examiner's rationale for why the Loretti reference teaches the claimed range with sufficient specificity is merely a conclusory statement based on a single endpoint overlap. Also, contrary to the Examiner's assertion, Appellant's reference to the preferred embodiments of the '433 Loretti patent is NOT to "argue that the reference did not teach others". Indeed, Appellant merely relies on the preferred embodiment as an example to further show that the claimed range is not disclosed in the cited reference with "sufficient

specificity to constitute an anticipation under the statute" in light of the Federal Court's decision in *Atofina v. Great Lakes Chem. Corp.*

With respect to anticipation of ranges, MPEP 2131.03 (II) states:

. . . In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. (emphasis added).

Appellant notes that the Examiner's foundation for "sufficient specificity" is built on a single endpoint overlap between the claimed range of 20 to 40  $\mu\text{m}$  and the referenced broader range of 40 to 100  $\mu\text{m}$ . Appellant respectfully submits that a comparison of facts of the instant case relative to the cited case law, as set forth in the following Table A, can only lead to the conclusion that the '443 Lorette reference does NOT disclose the claimed thickness range with sufficient specificity to anticipate the claimed thickness range.

Table A: Comparison of facts between the applied case law and the instant case:

	<b>Atofina v. Great Lakes Chem. Corp. (Fed. Cir. 2006)</b>	<b>Instant case</b>
<b>Claimed range</b>	330 to 450 °C	20 to 40 $\mu\text{m}$
<b>Referenced broad range</b>	100 to 500 °C	40 to 100 $\mu\text{m}$
<b>Referenced preferred range</b>	150 to 350 °C	45 to 75 $\mu\text{m}$
<b>Value given in Examples</b>	not available	50 $\mu\text{m}$

In *Atofina*, the prior art discloses a broad temperature range of 100 to 500 °C, which fully encompasses the claimed temperature range of 330 to 450°C. The prior art further discloses a preferred temperature range of 150 to 350°C, which overlaps with the claimed temperature range.

The Federal Court held that the temperature range of 100 to 500 °C disclosed by the prior art does not describe the claimed range of 330 to 450 °C with "sufficient specificity" to anticipate the claimed range. In support of its decision, the Court cited:

It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus. See, e.g., *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). There may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus. . . Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006).

The Federal Court also held that the preferred temperature range of 150 to 350°C which overlaps with the claimed temperature range does not anticipate the claimed temperature range. In support of its decision, the Court cited:

The disclosure of a range of 150 to 350C does not constitute a specific disclosure of the endpoints of that range, i.e., 150C and 350... The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the endpoints of the range than it is of each of the intermediate points. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006).

Appellant respectfully submits that the facts of the instant case are analogous to the situation contemplated by the Atofina Court.

First, the instant case deals with a claimed narrow species (i.e., outer layer having a thickness of from 20 to 40 µm) and a prior art reference disclosing a broad genus (i.e., an outer layer of thickness of 40 to 100 µm, made of polyamide 11, commercially available under the tradename of Rilsan (Col. 2, lines 53-54) and/or polyetherblock amide, commercially available under the trademark of Pebax® (Col. 2, lines 55-56). The Atofina Court held a broad genus range CANNOT anticipate a much narrower species. Appellant notes that in the cited case, the referenced broad range of 100 to 500 °C is about 3 times larger than the claimed range of 330 to 450 °C. Compared to the instant case, the referenced range of 40 to 100 µm is 3 times larger than the claimed range of 20 to 40 µm. Thus, in light of the Atofina Court's decision, Appellant submits that "given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim."

Second, in light of the Court's decision, Appellant submits that "the disclosure of a range of [40 to 100 $\mu$ m] does not constitute a specific disclosure of the endpoints of that range. i.e., [40 and 100]... The disclosure is only that of a range, not a specific [value] in that range, and the disclosure of a range is no more a disclosure of the endpoints of the range than it is of each of the intermediate points". Thus, the thickness range of 40 to 100  $\mu$ m disclosed by the prior art does not describe the claimed thickness range with sufficient specificity to anticipate the claimed range.

Furthermore, the broad referenced temperature range of 100 to 500 °C fully encompasses the claimed temperature range of 150 to 350°C, and the preferred temperature range of 150 to 350°C overlaps the claimed temperature range. In this case, other than the single overlap endpoint, the claimed thickness range is not disclosed anywhere in the entire '443 Lorette reference. Therefore, Appellant respectfully submits that the Examiner's basis for "sufficient specificity" is incompatible with the Atofina decision and conflicts with the well-established case law governing anticipation of ranges between a claimed narrow species and a broad genus disclosed by the prior art.

In view of the foregoing, Appellant respectfully submits that the '443 Lorette reference does not disclose the claimed thickness range of 20 to 40  $\mu$ m with "sufficient specificity to constitute anticipation under the statute".

Anticipation requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently. *Perricone v. Medicis Pharm. Corp.*, 432 F. 3d 1368, 1376 (Fed. Cir. 2005). As the '443 Lorette reference fails to disclose an outer layer having a thickness of from 20 to 40  $\mu$ m, it fails to anticipate claim 1 as required by § 102(b). Claims 2-5, 13, 17 and 19 depend either directly or indirectly from claim 1, they too are allowable over the cited reference for at least the same reason.

Appellant further submits that contrary to the Examiner's assertion, the '443 Lorette reference does not inherently disclose the claimed limitations: (i) "an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m<sup>2</sup>d", and (ii) an outer layer "allowing desorption of water absorbed in the intermediate layer during sterilization layer during sterilization after said sterilization at 121°C".

2. The claimed properties are not inherent in the multilayer film disclosed by Lorette

In relying on Loretta to disclose properties of the claimed multilayer film, properties that are NOT disclosed in the cited reference, the Examiner takes the position that:

...such properties limitations are inherent in the multilayer structure taught by Loretta given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film [are] identical to that of the claimed multilayer film. (Page 4, final Office Action, emphasis added)

With respect to inherent properties, MPEP 2112 states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic..."To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' (Emphasis added).

In other words, to state that the claimed properties are inherent to the referenced multilayer film, the claimed properties should be consistently present for the entire disclosed thickness range, as inherency may not be established by probabilities or possibilities. Moreover, the prior art must disclose materials that necessarily and predictably give rise to the same claimed properties at all times, and not by chance or probabilities.

A comparison of elements between the '443 Loretta reference and the instant application set forth in Table B (shown below) illustrates that Loretta does not disclose, among other things, claimed elements 3, 4 and 5.

With regard to claimed element 3, as set forth above, the thickness range of 40 to 100  $\mu\text{m}$  disclosed by the '443 Loretta reference does not describe the claimed range with sufficient specificity to anticipate the claimed range as required by MPEP § 2131.03 (II).

Claimed element 4, characterizing the claimed outer layer as: "allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C", is a characteristic that results from both the thickness and the material from which the outer layer is made of, in this case, PET. (See, e.g., specification at page 12, lines 21-29). As set forth above, the thickness range of the outer layer disclosed by Loretta does not anticipate the claimed thickness range. In other words, the claimed outer layer is distinct from the referenced outer layer. The difference in thickness alone is sufficient to negate the Examiner's basis for anticipation by inherency: "... the structure of the [referenced] multilayer film [...] is identical to that of the claimed multilayer film" (Final Office Action, page 6, Examiner's Answer, page 8). "Anticipation by inherent disclosure is appropriate only when the reference discloses prior art

that MUST NECESSARILY include the unstated limitation.” *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002), (emphasis added). As one out of the three layers of the claimed multilayer film is clearly distinct from the referenced multilayer film, the structure of the referenced film CANNOT be identical to that of the claimed multilayer film. Thus, the ‘443 Lorette reference cannot inherently disclose the properties of the claimed multilayer film.

In rebutting Appellant’s argument that the cited references fail to show certain features of the invention, the Examiner explained the following in support for her position on inherency:

. . . it is noted that the features upon which Appellants are relying on (i.e. a polyethylene terephthalate outer layer) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. (Examiner’s answer, page 9)

Appellant respectfully submits that the Examiner’s position is in error. Indeed, the limitation “allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C”, is a characteristic that results from both the thickness and the material from which the outer layer is made of, in this case, PET. Even if the material of the claimed outer layer is not explicitly recited, the claimed properties inherently call out only a finite possible number of materials, possibly even one combination of materials, or maybe even a single material. In this case, the specification discloses PET as an example of an outer material that produces the claimed property. There is no scientific or factual support that Lorette’s disclosed outer layer, made of polyamide 11, commercially available under the tradename of Rilsan (Col. 2, lines 53-54) and/or polyetherblock amide, commercially available under the trademark of Pebax® (Col. 2, lines 55-56), produces the claimed properties.

In the Examiner’s Answer, the Examiner further explained the following regarding her interpretation of inherency:

Furthermore, the Examiner has taken the inherency position given that that the structure of the claimed multilayer film (i.e., the number of layers, etc.) and the chemical composition of the claimed multilayer film are identical. Furthermore, once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection has been made, the burden shifts to the Applicants to show the unobvious difference. (Examiner’s Answer, page 8).

The remarks clearly demonstrate errors in the Examiner's position. First, the Examiner claims that the "structure of the claimed multilayer film" and "the chemical composition of the claimed multilayer film are identical" to Loretta while also contends that claims 1 and 20 do not recite a specific outer layer, i.e., a polyethylene terephthalate outer layer. (See, e.g., page 8 of the Examiner's Answer). Appellant questions how the "chemical composition" could be identical when it was not claimed.

Second, both independent claims 1 and 20 expressly recite physical properties of a multilayer film, i.e., (i) "an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m<sup>2</sup>d", and (ii) an outer layer "allowing desorption of water absorbed in the intermediate layer during sterilization layer during sterilization after said sterilization at 121°C". Claims 1 and 20 did not merely speculate or rely on inherency on certain physical properties but expressly call out limitations of the claimed multilayer film. As such, the prior art, to reject claims 1 and 20 under 35 USC §102, must show the same physical properties or show that the physical properties are inherent in the disclosed prior art multi-layer film. Here, the Examiner's only proof is that there is overlapping film layer thicknesses between the claimed film and the prior art and nothing else. Using the Examiner's logic, a multi-layer paper film having the same thicknesses for its different layers would inherently have the same properties as the claimed multi-layer film. However, a person of ordinary skill in the art would know better and know that paper has different properties than thermoplastic.

Thus, Appellant submits that the claimed property cannot be inherent in Loretta's outer layer because it has a different thickness range and it is made from a different material, namely Polyamide 11 or polyetherblock amide (Loretta, Col. 2, lines 29-44). The Examiner has not shown with particularity and consistency required by law that Polyamide 11 or polyetherblock amide is capable of producing a layer that allows desorption of water absorbed in the intermediate layer during sterilization after sterilization at 121°C. As the referenced outer layer has a distinct thickness range AND is made from a different material, it cannot inherently anticipate the resulting property of the claimed multilayer.

Furthermore, in a three-layer film disclosed by Loretta, the Examiner has not shown with adequate consistency that the combination with Polyamide 11 or polyetherblock amide outer layer produces the claimed properties. In other words, the outer layer itself must produce a required characteristic in order for the combination with the middle and inner layers to produce the claimed properties.

Similarly, Loretti cannot be said to inherently disclose claimed element 5, which is a property resulted from a combination of claimed elements 1, 2, 3 and 4. It is undisputable that Loretti does not disclose the combination of elements 3-4. As such, Loretti cannot be relied on to inherently disclose element 5.

Still furthermore, the Examiner seems to be improperly mixing anticipation concepts under §102 with obviousness concepts under §103 when she states: "Furthermore, once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection has been made, the burden shifts to the Applicants to show the unobvious difference." (Examiner's Answer, page 8). Under §102, the single prior art reference must disclose each and every element of the claim under consideration. Anticipation is established only when a single prior art reference discloses, expressly or under the principle of inherency, every element of a claimed invention as well as disclosing structure which is capable of performing the recited functional limitations. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984), cert dismissed, 468 U.S. 1228 (1984); *W.L. Gore and Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), cert denied, 469 U.S. 851 (1984).

Thus, the only issue should be whether Loretti discloses with particularity and consistency required by law that Polyamide 11 or polyetherblock amide, or in combination with a middle layer and an inner layer, is capable of producing a multi-film layer that allows desorption of water absorbed in the intermediate layer during sterilization after sterilization at 121°C. Appellant submits that the Examiner has failed to meet her burden.

Table B:

Disclosed	Claimed elements	Prior art	
	1. Inner layer: 30 to 120 $\mu\text{m}$ ;	yes	
	2. intermediate layer: 5 to 35 $\mu\text{m}$ ;	yes	
Outer layer made of PET	3. Outer layer: 20 $\mu\text{m}$ to 40 $\mu\text{m}$ ;	40 to 100 $\mu\text{m}$	Polyamide 11 or polyetherblock amide
	4. Allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 $^{\circ}\text{C}$ ;	no	
	5. Oxygen transmission rate at 23 $^{\circ}\text{C}$ through multilayer is less than 0.7 $\text{ml}/\text{m}^2 \text{ d}$ .	no	

In summary, Appellant respectfully submits that Loretta does not disclose a multilayer film with the claimed thickness range of 20-40  $\mu\text{m}$  that can be used as an outer layer that allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121  $^{\circ}\text{C}$  and when used in combination with an inner layer and an intermediate layer of the claimed characteristics, produces an oxygen transmission rate at 23  $^{\circ}\text{C}$  through the multilayer film of less than 0.7  $\text{ml}/\text{m}^2 \text{ d}$ . As illustrated in Table B, the claimed property of the instant outer layer, "allow[ing] desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121  $^{\circ}\text{C}$ ", results from among other factors, the material from which the outer layer is made of as well as its thickness, namely a PET outer layer and a thickness range of from 20 to 40  $\mu\text{m}$ . In contrast, Loretta's outer layer not only has a different thickness range, 40 to 100  $\mu\text{m}$ , but also is made of a different material, a polyamide 11 and/or polyetherblock amide (Loretta, Col. 2, line 38).

MPEP 2112.IV further states: "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

In this case, other than providing a single overlapping point as evidence of inherency, Appellant respectfully submits that the Examiner has not fulfilled her burden of proof to clearly show how a referenced outer layer, made of a different material, having a different thickness range, will necessarily possess the same properties as the claimed multilayer film. Inherency may not be established by probabilities or possibilities. Based on the undisputable fact that there is no guarantee that a referenced multilayer film made of a different material, having a different thickness range will necessarily, consistently and predictably have the same characteristics as a claimed multilayer film, Appellant respectfully submits that the claimed properties are not inherent to the referenced multilayer film.

In view of the foregoing, Appellant respectfully reiterates that the '443 Lorette reference does not disclose: (1) an oxygen transmission rate at 23° C of less than 0.7ml/ m<sup>2</sup>d; (2) an outer layer having a thickness of from 20 to 40  $\mu\text{m}$ . (3) the outer layer allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C. Thus, the '443 Lorette reference fails to anticipate claim 1 under § 102(b).

Claims 2-5, 13, 17 and 19 depend either directly or indirectly from claim 1; therefore they too are allowable over the cited reference for at least the same reasons.

## **2. Lorette does not anticipate claims 20, 22 and 23**

Of the other appealed claims, previously presented independent claim 20 recites:

20. (Previously Presented) A method for forming a multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, having an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m<sup>2</sup>d, the method comprising:  
    providing an inner layer, being in contact with the content of the container, having a thickness of from 30 to 120  $\mu\text{m}$ ;  
    providing an outer layer, facing the environment, having a thickness of from 20 to 40  $\mu\text{m}$ ;  
    providing an intermediate layer, interposed between the inner layer and the outer layer, having a thickness of from 5 to 35  $\mu\text{m}$ ; and  
    wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

Claim 20 is directed to a method for forming a multilayer film. Similar to claim 1, the multilayer film formed by the claimed method comprises, among other things: (1) an outer layer having a thickness range of from 20 to 40  $\mu\text{m}$ ; (2) an oxygen transmission rate at 23°C through

the multilayer film of less than 0.7ml/m<sup>2</sup>d; and (3) wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

In rejecting claims 20, 22 and 23, the Examiner alleges that all the limitations of the rejected claims are either disclosed or inherent in the '443 Lorette reference (Final Office Action, pages 5-6, Examiner's Answer, pages 3-4).

As set forth above, the '443 Lorette reference does not disclose the claimed thickness range of from 20 to 40 µm with sufficient specificity to anticipate the claimed range under the statute. Furthermore, as the outer layer of the film formed from the claimed method is distinct from the referenced outer layer, the property limitations of the multilayer film formed from the claimed method are not inherent in Lorette's multilayer film. Thus, the '443 Lorette reference fails to disclose each and every element of the claimed method and therefore fails to anticipate claim 20 under § 102(b). Claims 22 and 23 depend from claim 20, therefore they too are allowable over the cited reference for at least the same reason.

**II. Rejections of claims 6, 18 and 21 under § 103(a) over Lorette in view of Högström (second issue)**

The Examiner rejected claims 6, 18 and 21 as being unpatentable over Lorette in view of Högström. Appellant respectfully submits that Lorette in view of Högström does not render the appealed claims obvious under § 103(a). Claims 6, 18 and 21 are argued separately.

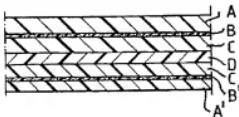
In rejecting claims 6, 8 and 21, the Examiner contends that Lorette discloses the claimed elements as previously discussed but does not teach that the outer layer may be a polyethylene terephthalate layer. Högström discloses an outer layer made of polyolefins, polyethylene terephthalates. The Examiner concludes that it would have been obvious for one having ordinary skill in the art to incorporate a polyethylene terephthalate outer layer in the multilayer film taught by Lorette (Final Office Action, pages 6-7, Examiner's Answer, pages 4-5).

The '443 Lorette reference is discussed above.

**The '566 Högström reference**

The '566 Högström reference discloses a multi-layer film, substantially impermeable to oxygen and autoclavable, comprising the following layers A-B-C-D-C-B'-A', as shown in Fig. 1, reproduced below:

Fig.1



The outermost layers A and A' face the environment and the goods inside the container, respectively (Col. 2, lines 57-59). They can be made from the same or different polyolefines or PET (polyethylene-terephthalate) or copolymers of PET (Col. 3, lines 1-3).

Högström specifically teaches:

[For the outer layers A and A', polypropylene is especially preferred if the multilayer film shall be subjected to steam sterilization, but if sterilization by irradiation is for some reason desirable, polyethenes are the suitable choice for layers A and A', since polypropylenes are not sterilizable with irradiation. (Col. 5, lines 22-27).]

Högström compares the oxygen permeability of seven films formed from different materials (Table 3, Col. 6, lines 30-41) and the results are summarized in Table 1 (Col. 6, line 56 to Col. 7, line 9, reproduced below):

Table 1 shows the oxygen permeability measured in cubic centimeters per square meter, day and bar for Films 1-7 at different temperatures and different relative humidity.

Permeability (before sterilization)	
Ox. 23° C/60% RH ccm <sup>3</sup> /day/bar	Ox. 50° C/20%/RH ccm <sup>3</sup> /day/bar
Film 1 ≤0.5	8.0
Film 2 5.00	
Film 3 38.00	185.00
Film 4 37.00	175.00
Film 5 13.50	4.50
<hr/>	
Permeability (before sterilization)	
Ox. 23° C/60% RH ccm <sup>3</sup> /day/bar	Ox. 50° C/20%/RH ccm <sup>3</sup> /day/bar
Film 6 0.84	6.00
Film 7 0.84	5.00

Table 3:

The seven tested film materials are:  
 Film 1: polypropylene (PP)/EVOH; 30% ethene/  
 polypropylene (PP)  
 Film 2: PE/EVOH; 44% ethene/PP  
 Film 3: PP/polyamide: XE 3303 (PA)/PP  
 Film 4: Polyethen (PE)/PA (as in Film 3)/PE  
 Film 5: PE/polyamide: 80% MXD6 and 20% XE 3303  
 (PA)/EVOH; 33% ethene/PA (same)/PE  
 Film 6: PP/PA (polyamide 6)/a copolymer containing  
 EVOH/PP  
 Film 7: Polyethylene terephthalate (PET)/glass/PET/PP

As shown in Table 1, among all the films tested, film 7 has an outer layer made of polyethylene terephthalate (PET), but the ones with superior oxygen permeability at 23°C, which is the temperature of normal use, are films 1 and 5. The outer layer of film 1 is made of polypropylene and the outer layer of film 5 is made of Polyethylene (PE)/polyamide.

**Loretti in view of Högström fails to render claims 6 obvious under § 103(a)**

Claim 6 depends from claim 1. As set forth above, Loretti fails to anticipate claim 1 under § 102(b) as it fails to disclose each and every element of the claim under consideration. As Högström is merely relied on to disclose a polyethylene terephthalate layer, it does not make up for the deficiencies of Loretti. The cited references, even if combinable, a position that Appellant does not concede, still fail to disclose or suggest all the elements and limitations of independent claim 1 and thus fail to render claim 1 obvious under § 103(a). As claim 6 depends from claim 1, it too is allowable over the cited references for at least the same reason.

Furthermore, Högström teaches a polypropylene outer layer when the container is to be subjected to steam sterilization. (Högström, Col. 5, lines 22-27). By selectively picking and choosing a PET outer layer when Högström clearly prefers a polypropylene outer layer for steam sterilization, the Examiner failed to articulate a rational underpinning for the combination. "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex, Inc.*, 550 U.S. at \_\_\_, 82 USPQ2d 1385, 1396 (2007). Moreover, by not providing a rational underpinning, the rejection appears to be an inappropriate hindsight evaluation.

Still furthermore, Loretti discloses an outer layer made from Polyamide 11 or polyetherblock amide with a thickness of 40 to 100 µm. Högström teaches a seven layer film (A-B-C-D-C-B'-A') in which the outer layer is 20-100 µm and most preferably 45-55 µm. (Högström, Col. 5, lines 37-38). Even if Högström's outer layer (i.e., PET) can be substituted for Loretti's outer layer (i.e.; polyamide or polyetherblock amide), there is still no suggestion or teaching that the PET layer should be held at the same thickness range as the claimed thickness range of 20 to 40 µm. Among other things, the range taught by Högström is for a seven (7) layer film. Surely, if a different material is used (for example, using the PET outer layer from Högström instead of polyamide or polyether block amide for the Loretti film), a different

thickness range will ensue as different material types produce different yield, different material combinations produce different yield, and different number of layers produce different yield. In other words, by combining Högström with Loretti, a “new” film is produced. The “new” film will require specific thicknesses for the outer, middle, and inner layers to produce the same properties as the claimed properties (namely: the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C; and an oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer of less than 0.7ml/m<sup>2</sup>d). However, the Examiner failed to explain how the “new” film would have the same properties as the claimed properties without first explaining how the film thicknesses are obtained. Again, this should be a second test after satisfying the requirement of articulating a rational underpinning for the combination, which the Examiner has not done especially in light of Högström’s preference for using a polypropylene (PP) outer layer when the container is to be subjected to steam sterilization.

As the Examiner failed to set forth a *prima facie* case of obviousness by not articulating why a certain thickness range would have been chosen when the number of layers would reduce from seven (7) to three (3) in substituting the PET from Högström for the outer layer of the three layer film from Loretti, the combination failed to render claims 1 and 6 obvious.

**Loretti in view of Högström fails to render claims 21 obvious under § 103(a)**

Claim 21 depends from claim 20. As set forth above, Loretti fails to anticipate claim 20 under § 102(b) as it fails to disclose each and every element of the claim under consideration. As Högström is merely relied on to disclose a polyethylene terephthalate layer, it does not make up for the deficiencies of Loretti. The cited references, even if combinable, a position that Appellant does not concede, still fail to disclose or suggest all the elements and limitations of independent claim 20 and thus fail to render claim 20 obvious under § 103(a). As claim 21 depends from claim 20, it too is allowable over the cited references for at least the same reasons.

Furthermore, Högström teaches a polypropylene outer layer when the container is to be subjected to steam sterilization. (Högström, Col. 5, lines 22-27). By selectively picking and choosing a PET outer layer when Högström clearly prefers a polypropylene outer layer for steam sterilization, the Examiner failed to articulate a rational underpinning for the combination.

"[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex, Inc.*, 550 U.S. at \_\_\_, 82 USPQ2d 1385, 1396 (2007). Moreover, by not providing a rational underpinning, the rejection appears to be an inappropriate hindsight evaluation.

Still furthermore, Loretti discloses an outer layer made from Polyamide 11 or polyetherblock amide with a thickness of 40 to 100  $\mu\text{m}$ . Högström teaches a seven layer film (A-B-C-D-C'-B'-A') in which the outer layer is 20-100  $\mu\text{m}$  and most preferably 45-55  $\mu\text{m}$ . (Högström , Col. 5, lines 37-38). Even if Högström's outer layer (i.e., PET) can be substituted for Loretti's outer layer (i.e.; polyamide or polyetherblock amide), there is still no suggestion or teaching that the PET layer should be held at the same thickness range as the claimed thickness range of 20 to 40  $\mu\text{m}$ . Among other things, the range taught by Högström is for a seven (7) layer film. Surely, if a different material is used (for example, using the PET outer layer from Högström instead of polyamide or polyetherblock amide for the Loretti film), a different thickness range will ensue as different material types produce different yield, different material combinations produce different yield, and different number of layers produce different yield. In other words, by combining Högström with Loretti, a "new" film is produced. The "new" film will require specific thicknesses for the outer, middle, and inner layers to produce the same properties as the claimed properties (namely: the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C; and an oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer of less than 0.7ml/m<sup>2</sup>d). However, the Examiner failed to explain how the "new" film would have the same properties as the claimed properties without first explaining how the film thicknesses are obtained.

As the Examiner failed to set forth a *prima facie* case of obviousness by not articulating why a certain thickness range would have been chosen when the number of layers would reduce from seven (7) to three (3) in substituting the PET from Högström for the outer layer of the three layer film from Loretti, the combination failed to render claims 20 and 21 obvious.

**Loretti in view of Högström fails to render claims 18 obvious under § 103(a)**

Of the rejected claims, previously presented independent claim 18 recites:

18. (Previously Presented) A multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, comprising:

an inner layer consisting essentially of non-polar polymeric material;

an outer layer facing the environment, said outer layer comprising at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer; and

an intermediate layer, interposed between the inner layer and the outer layer, said intermediate layer comprising ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%

In rejecting claim 18, the Examiner contends that Loretti teaches an inner layer and an intermediate layer as claimed and the Examiner relies on Högström to disclose an outer layer made from PET or PET copolymer. (final Office Action, pages 6-7, Examiner's Answer, pages 4-5).

A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. In *United States v. Adams*, 383 U.S. 39, 40, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293 (1966). In *KSR International Co v. Teleflex, Inc.*, while emphasizing a more flexible approach to the teaching, suggestion, motivation ("TSM") test, the Supreme Court however acknowledged the importance of "identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way the claimed new invention does...**because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known". *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Appellant respectfully submits that even if combinable, a position that Appellant does not concede, one of ordinary skill in the art would not have been motivated to combine the cited references in the manner suggested to arrive at the claimed multilayer film. Furthermore, the Examiner has failed to provide an articulated reasoning with some rational underpinning as to why one of ordinary skill in the art would have selectively incorporated Högström's PET layer into Loretti's multilayer film to produce the multilayer film recited in claim 18.

In rebutting Appellant's position that Högström does not teach using PET as an outer layer for a multilayer film for use in steam sterilization, the Examiner states the following:

Again, the Examiner would like to point out that the entire disclosure of a prior art reference and not just the preferred embodiments can be relied on to reject the claims. Furthermore, . . . the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to one having ordinary skill in the art to use a polyethylene terephthalate outer layer in the multilayer film taught by Loretta given that Högström et al teach it is desirable to have an outermost layer that front the environment in an autoclavable multi-layer and is made from polyethylene terephthalate which is a moisture resistant material capable of withstanding both water vapor and liquid water. (Examiner's Answer, pages 9-10).

Appellant respectfully disagrees with the Examiner's position. “[T]he test [for obviousness] is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In Sovich*, 769 F. 2d at 742-43. Therefore, Appellant's reference to specific disclosure within the cited references, such as for example Table 1 of Högström, is to establish what the teachings of the references would have suggested to one of ordinary skill in the art. As further discussed below, contrary to the Examiner's assertion, from the teachings of Loretta and Högström, one of ordinary skill in the art would not have incorporated Högström's PET outer layer into Loretta's multilayer film to produce the claimed multilayer film.

Furthermore, Appellant submits that the Examiner has failed to articulate a rational reasoning with some rational underpinning to show why it would have been obvious to one of ordinary skill in the art to modify Loretta's multilayer film in view of Högström to produce the claimed multilayer film. A generic statement that it would have been obvious to one skill in the art to do so “since Högström et al teach it is desirable to have an outermost layer that front the environment in an autoclavable multi-layer and is made from polyethylene terephthalate which is a moisture resistant material capable of withstanding both water vapor and liquid water” is a mere conclusory statement without support. Indeed, in his disclosure, Högström clearly teaches a polypropylene outer layer for a multilayer film intended for steam sterilization and Loretta's multilayer film is made for steam sterilization. As the Examiner has repeatedly stated in the Examiner's Answer, “Applicant must look to the whole reference for what it teaches” (Examiner's Answer, pages 7 and 9). Appellant submits that to establish what the prior art would have suggested to a skilled artisan, the disclosure of the cited reference as a whole must be

considered, including portions that teach away from the invention. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention" (§MPEP 2141.02 (VI)). As further discussed below, from the combined teachings of Loretta and Högström, a skilled artisan would not have incorporated Högström's PET outer layer into Loretta's multilayer film to produce the claimed multilayer film.

As set forth above, Loretta specifically teaches:

*... Preferred sterilization methods are the sterilization at a temperature at 121 °C for a period of time which ensures sterility in steam-type autoclaves or in a water cascade, or the sterilization with ethylene oxide.* (Loretta, Col. 4, lines 2-5).

Loretta specifically cautions:

*The core of the three- layered structure of the blown film according to the invention is the ethylene/vinyl alcohol copolymer layer b) with a defined ethylene content of 27 to 38 mol %. Namely, if the ethylene content is chosen too high, the ethylene/vinyl alcohol copolymer layer b) is destroyed in the usual steam sterilization and [loses] its gas barrier properties so that the object of the invention cannot be achieved satisfactorily.* (Loretta, Col. 3, lines 2-6, emphasis added).

Thus, the '443 Loretta reference would have suggested to one of ordinary skill in the art that the usual and preferred method of sterilization for Loretta's multilayer film is steam sterilization. Specifically, Loretta would have suggested to one of ordinary skill in the art that the defined ethylene content of 27 to 38 mol % of the intermediate layer is suitable for steam sterilization, and more importantly, any changes in this ethylene content would compromise its gas barrier property in the "usual steam sterilization". Thus, Loretta would have alerted one of ordinary skill in the art that any change in the composition of the multilayer film, as simply as a mere change in the ethylene content, could destroy its gas barrier properties during steam sterilization. From Loretta's teachings, one of ordinary skill in the art would have been warned that the composition of the layers is critical in achieving a targeted gas barrier property. Thus, from Loretta's teachings, one of ordinary skill in the art would not have arbitrarily changed the composition of Loretta's multilayer film or its method of sterilization without a scientific reason to do so.

As set forth above, the '566 Högström reference teaches that the outermost layers A and A' can be made of polyolefines, polyethylene-terephthalate (PET) or PET copolymers. However,

Högström would have cautioned one of ordinary skill in the art that the choice of materials used for the outer layer dictates the sterilization method, as described below:

*. . . The polyolefines should be both moisture resistant and resistant for sterilization by irradiation, examples of such materials are the polypropylene WB8052C from Neste and various polyethenes. Polypropylene is especially preferred if the multilayer film shall be subjected to steam sterilization, but if sterilization by irradiation is for some reason desirable, polyethenes are the suitable choice for layers A and A', since polypropylenes are not sterilizable with irradiation. (Högström, Col. 5, lines 18-27).*

Thus, the '566 Högström reference would have suggested to one of ordinary skill in the art that not all materials are suitable for a particular sterilization method and thus the choice of materials for the outer layer should not be made arbitrarily but instead should be made in view of the desired method of sterilization.

Furthermore, Table 1 of the '566 Högström reference (reproduced above) would have informed one of ordinary skill in the art that among the seven films tested, films 1 and 5 have the best oxygen impermeability at 23°C, which is the ambient temperature. Of those films, film 1 has a polypropylene outer layer, which is "especially preferred if the multilayer film shall be subjected to steam sterilization". Even if the next best film is selected, i.e., film 5, a person of ordinary skill in the art would have selected PE.

The combined teachings of Loretti and Högström would have suggested to one of ordinary skill in the art that: (1) Loretti's multilayer film is intended for steam sterilization and the defined ethylene content of 27 to 38 mol % (Loretti, Col. 3, lines 1-6) is optimized for such method of sterilization; (2) Högström's outer layers that are suitable for a multilayer film intended for steam sterilization are polypropylene (Högström, Col. 5, lines 22-23). The data presented in Table 1 of the '566 Högström reference would have further justified to an artisan the choice of polypropylene for the outer layer since film 1, which has a polypropylene outer layer, has a superior oxygen permeability at ambient temperature than its counterparts, including film 7 which has an outer layer made of PET. As such, the teachings of the cited references would have actually taught an artisan away from the instant claim. [R]eference[s] may be said to teach away when a person of ordinary skill, upon reading the reference[s], would be discouraged from following the path set out in the reference[s], or would be led in a direction divergent from the path that was taken by the applicant". *In re Gurley*, 27 F. 3d 551, 553 (Fed. Cir. 1994). Also, the multilayer film disclosed by Högström has seven (7) different layers. Thus, Högström may

not even teach an outer layer made of PET had his invention been directed to a three layer film. The Examiner has not shown why a PET outer layer would still be used in a three layer film

In rejecting claims under 35 U.S.C. § 103(a), the Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-87 (Fed. Cir. 1984).

Thus, the burden is on the Examiner to identify and articulate a reason why one of ordinary skill in the art would have been led to selectively add a PET outer layer to Loretti's multilayer film when: (1) Loretti specifically teaches steam sterilization for its multilayer film; (2) Högström specifically teaches a polypropylene outer layer for a multilayer film subjected to steam sterilization; and (3) both cited references explicitly cautioned that not all materials are suitable for a desired method of sterilization and any changes in the composition of the layers may compromise a targeted gas barrier property.

The Examiner has failed to cite disclosure in the references to support her assertion, or to provide a convincing line of reasoning as to why an artisan would have found the claim recitations to be obvious in light of the teaching of the cited references. Thus, Appellant respectfully submits that the Examiner has not adequately explained why one of ordinary skill in the art would have been led to combine selective teachings from Högström with Loretti in the manner suggested to arrive at the claimed multilayer film.

"[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex, Inc.*, 550 U.S. at \_\_\_, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

In view of the foregoing, Appellant respectfully submits that the Examiner has failed to articulate a reason with rational underpinning to support the legal conclusion that one of ordinary skill in the art would have combined the cited references in the manner suggested to produce the claimed multilayer film. As such, the Examiner has not established a *prima facie* case of obviousness and thus the rejection of claim 18 under § 103(a) cannot be maintained.

**III. Rejections of claims 7-12 and 24 under § 103(a) over Loretty in view of McKedy (third issue)**

The Examiner rejected claims 7-12 and 24 as being unpatentable over Loretty in view of McKedy. In rejecting claims 7-12 and 24, the Examiner contends that Loretty discloses the claimed elements as previously discussed but does not teach an oxygen absorber such as iron salts. McKedy discloses an improved oxygen-absorbing composition which includes particulate annealed electrolytically reduced iron which will provide a more rapid rate of oxygen absorption than plain electrolytically reduced iron (McKedy, Col. 1, lines 22-25). The Examiner concludes that it would have been obvious for one having ordinary skill in the art to incorporate an oxygen absorber to any of the layers of the multilayer film taught by Loretty (Final Office Action, pages 7-8; Examiner's Answer, pages 5-6).

Of the rejected claims, claims 7-12 are argued together; and claim 24 is argued separately.

**Loretty in view of McKedy fails to render claims 7-12 obvious under § 103(a)**

Claim 7-12 depend either directly or indirectly from claim 1. As set forth above, Loretty fails to anticipate claim 1 under § 102(b) as it fails to disclose each and every element of the claim under consideration. As McKedy is merely relied on to disclose an oxygen absorbing composition, it does not make up for the deficiencies of Loretty. The cited references, even if combinable, a position that Appellant does not concede, still fail to disclose or suggest all the elements and limitations of independent claim 1 and thus fail to render claim 1 obvious under § 103(a). As claims 7-12 depend either directly or indirectly from claim 1, they too are allowable over the cited references for at least the same reasons.

**Loretty in view of McKedy fails to render claims 24 obvious under § 103(a)**

Claim 24 depends from claim 20. As set forth above, Loretty fails to anticipate claim 20 under § 102(b) as it fails to disclose each and every element of the claim under consideration. As McKedy is merely relied on to disclose an oxygen absorbing composition, it does not make up for the deficiencies of Loretty. The cited references, even if combinable, a position that Appellant does not concede, still fail to disclose or suggest all the elements and limitations of

independent claim 20 and thus fail to render claim 20 obvious under § 103(a). As claim 24 depends from claim 20, it too is allowable over the cited references for at least the same reasons.

**Conclusion**

In view of the foregoing remarks, Appellant respectfully submits that claims 1-13 and 17-24 are patentable over the cited references and allowance is respectfully solicited.

Should the Examiner wish to speak with Appellant's attorney, she is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

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By \_\_\_\_\_

  
Tom H. Dao  
Reg. No. 44,641  
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THD/bcp

**CLAIM APPENDIX**

1. (Previously Presented) Sterilizable multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three-layered structure with an inner layer being in contact with the content of the container, an intermediate layer and an outer layer facing the environment, said layers optionally connected by tie and/or adhesive layers; wherein:

the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7 ml/m<sup>2</sup>d;

said inner layer having a thickness of from 30 to 120 µm;

said intermediate layer having a thickness of from 5 to 35 µm and said outer layer having a thickness of from 20 to 40 µm; and

allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

2. (Original) The multilayer film according to claim 1, wherein said oxygen transmission rate at 23 °C is less than 0.4 ml/m<sup>2</sup>d.

3. (Previously Presented) The multilayer film according to claim 1, having an inner layer essentially consisting of non-polar polymeric material.

4. (Previously Presented) The multilayer film according to claim 3, having an inner layer comprising polypropylene homopolymer and/or polypropylene copolymer.

5. (Previously Presented) The multilayer film according to claim 1, having an intermediate layer comprising ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%.

6. (Previously Presented) The multilayer film according to claim 1, having an outer layer comprising polyethylene terephthalate homopolymer and/or polyethylene terephthalate copolymer.

7. (Previously Presented) The multilayer film according to claim 1, characterized in that the multilayer film contains at least one oxygen absorber within one or several of the layers.

8. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber contains Fe or Fe(II)-salts.

9. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in said inner layer.

10. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in a tie and/or adhesive layer located between said inner layer and said intermediate layer.

11. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in the respective layer/layers in an amount of 1 to 100 mg/g related to the weight of the respective layer.

12. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in an amount of 0.5 to 2.0 mg/g related to the overall weight of all layers.

13. (Previously Presented) Vapor sterilized multilayer film according to claim 1.

14. (Canceled)

15. (Canceled)

16. (Canceled)

17. (Previously Presented) The multilayer film according to claim 2, having an inner layer essentially consisting of non-polar polymeric material.

18. (Previously Presented) A multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, comprising:

an inner layer consisting essentially of non-polar polymeric material;

an outer layer facing the environment, said outer layer comprising at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer; and

an intermediate layer, interposed between the inner layer and the outer layer, said intermediate layer comprising ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%.

19. (Previously Presented) The multilayer of claim 17 wherein the outer layer has a thickness of from 20 to 40  $\mu\text{m}$ .

20. (Previously Presented) A method for forming a multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, having an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m<sup>2</sup>d, the method comprising:

providing an inner layer, being in contact with the content of the container, having a thickness of from 30 to 120  $\mu\text{m}$ ;

providing an outer layer, facing the environment, having a thickness of from 20 to 40  $\mu\text{m}$ ;

providing an intermediate layer, interposed between the inner layer and the outer layer, having a thickness of from 5 to 35  $\mu\text{m}$ ; and

wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

21. (Previously Presented) The method of claim 20, wherein the outer layer comprises at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer.

22. (Previously Presented) The method of claim 20, wherein the intermediate layer comprises ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%.

23. (Previously Presented) The method of claim 20, wherein the inner layer comprises polypropylene homopolymer and/or polypropylene copolymer.

24. (Previously Presented) The method of claim 20, further providing at least one oxygen absorber within one or several of the layers.